

1642\$

Practitioner's Docket No. U 013840-5

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of: OM REDDY GADDAM, et al.

Serial No.: 10/067,096

Group No.: 1642

Filed: February 4, 2002

Examiner.: --

For: PHARMACEUTICALLY ACCEPTABLE SALTS OF TRICYCLIC COMPOUNDS

Commissioner for Patents

P. O. Box 1450

Alexandria, VA 22313-1450

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TRANSMITTAL OF INFORMATION DISCLOSURE STATEMENT  
BEFORE MAILING DATE OF EITHER A FINAL ACTION  
OR NOTICE OF ALLOWANCE (37 C.F.R. 1.97(c))

NOTE: 37 C.F.R. 1.97: "(c) An information disclosure statement shall be considered by the Office if filed after the period specified in paragraph (b) of this section, provided that the information disclosure statement is filed before the mailing date of any of a final action under § 1.113, a notice of allowance under § 1.311, or an action that otherwise closes prosecution in the application, and it is accompanied by one of:

- (1) The statement specified in paragraph (e) of this section; or
- (2) The fee set forth in § 1.17(p)."

NOTE: "If a final action or notice of allowance is mailed in an application and later withdrawn, the application will be considered as not having had a final action or notice of allowance mailed for purposes of considering an information disclosure statement." Notice of April 20, 1992 (1138 O.G. 37-41, 39).

CERTIFICATION UNDER 37 C.F.R. 1.8(a) and 1.10\*

(When using Express Mail, the Express Mail label number is mandatory;  
Express Mail certification is optional.)

I hereby certify that, on the date shown below, this correspondence is being:

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- ☒ deposited with the United States Postal Service in an envelope addressed to the Commissioner for Patents, P. O. Box 1450, Alexandria, VA 22313-1450.

37 C.F.R. 1.8(a)

37 C.F.R. 1.10\* (Preferred)

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- ☐ transmitted by facsimile to the Patent and Trademark Office.

Date: September 9, 2003

Signature

JANET I. CORB

(type or print name of person certifying)

\* Only the date of filing (§ 1.6) will be the date used in a patent term adjustment calculation, although the date on any certificate of mailing or transmission under § 1.8 continues to be taken into account in determining timeliness. See § 1.703(f). Consider "Express Mail Post Office to Addressee" (§ 1.10) or facsimile transmission (§ 1.6(d)) for the reply to be accorded the earliest possible filing date for patent term adjustment calculations.

**NOTE:** 37 C.F.R. § 1.704(d): "A paper containing only an information disclosure statement in compliance with §§ 1.97 and 1.98 will not be considered a failure to engage in reasonable efforts to conclude prosecution (processing or examination) of the application under paragraphs (c)(6), (c)(8), (c)(9), or (c)(10) of this section if it is accompanied by a statement that each item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart application and that this communication was not received by any individual designated in § 1.56(c) more than thirty days prior to the filing of the information disclosure statement. This thirty-day period is not extendable."

**NOTE:** "If information submitted during the period set forth in 37 C.F.R. 1.97(c) with a certification is used in a new ground of rejection on unamended claims, the next Office action will not be made final since in this situation it is clear that applicant has submitted the information to the office promptly after it has become known and the information is being submitted prior to a final determination on patentability by the Office. However, the information submitted with a certification can be used in a new ground of rejection and the next Office action made final, [i]f the new ground of rejection was necessitated by amendment of the application by applicant. Where the information is submitted during this period with a fee, the examiner may use the information submitted, e.g., printed publication or evidence of public use, and make the next Office action final whether or not the claims have been amended, provided that no other new ground of rejection which was not necessitated by amendment to the claims is introduced by the examiner. See MPEP 706.07(a). If a new ground of rejection is introduced that is neither necessitated by an amendment to the claims nor based on the information submitted with the fee set forth in 37 C.F.R. 1.17(p), the Office action shall not be made final. Notice of April 20, 1992 (1138 O.G. 37-41, 39).

**WARNING:** "A petition for suspension of action to allow applicant time to submit an information disclosure statement will be denied as failing to present good and sufficient reasons, since 37 C.F.R. 1.97 provides adequate recourse for the timely submission of prior art for consideration by the examiner." Notice of July 6, 1992 (1141 O.G. 63). But see § 103(b) and (c), limited suspension of action in a continued prosecution application (CPA) filed under § 1.53(d) and in a request for continued examination (RCE) under § 1.114.

**WARNING:** No extension of time can be had under 37 C.F.R. 1.136(a) or (b) for filing an IDS. 37 C.F.R. 1.97(f).

### TIME OF TRANSMITTAL OF ACCOMPANYING INFORMATION DISCLOSURE STATEMENT

1. The information disclosure statement transmitted herewith is being filed **after** three months of the filing date of this national application or the date of entry of the national stage as set forth in § 1.491 in an international application or after the mailing date of the first Office action on the merits, whichever event occurred last but **before** the mailing date of either:

- (1) a final action under § 1.113 or
- (2) a notice of allowance under § 1.311,

whichever occurs first.

### STATEMENT OR FEE

2. Accompanying this transmittal is  
(check either A or B below)

A. ☐ a statement as specified in 37 C.F.R. 1.97(e).

OR

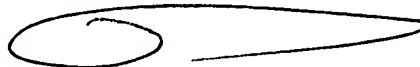
B. ☒ the fee set forth in 37 C.F.R. 1.17(p) for submission of an information disclosure statement under § 1.97(c). (\$180.00).

### METHOD OF PAYMENT OF FEE

3.

- ☒ Attached is a check in the amount of \$ 180.00.  
☐ Charge Account No. \_\_\_\_\_ in the amount of \$ \_\_\_\_\_.  
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If any additional fees are due, please charge Account 12-0425.



SIGNATURE OF PRACTITIONER

Reg. No. 33,778

JANET I. CORD

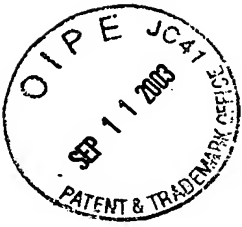
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New York, N.Y. 10023



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Attorney Docket No.: U 013840-5

Commissioner for Patents

P.O. Box 1450

Alexandria, VA 22313-1450

Sirs:

INFORMATION DISCLOSURE STATEMENT

We draw the attention of the Examiner to the attached references which were cited in the August 12, 2003 response to the Office Action mailed on February 12, 2003 and which are also listed on the attached Form PTO-1449.

Respectfully submitted,

JANET I. CORD  
LADAS & PARRY  
26 WEST 61<sup>ST</sup> STREET  
NEW YORK, NEW YORK 10023  
REG. NO. 33,778 (212) 708-1935

CERTIFICATE OF MAILING (37 CFR 1.8a)

I hereby certify that this paper (along with any paper referred to as being attached or enclosed) is being deposited with the United States Postal on the date shown below with sufficient postage as first class mail in an envelope addressed to the: Commissioner of Patents and Trademarks, Washington, D.C. 20231

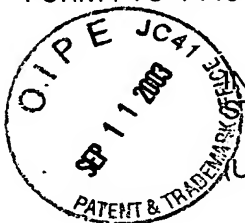
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FORM PTO-1449

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STATEMENT BY APPLICANT

(Use several sheets if necessary)

ATTY. DOCKET NO.

U 013840-5

SERIAL NO.

10/067,096

APPLICANT

OM REDDY GADDAM, et al.

FILING DATE

February 4, 2002

GROUP

1642

## REFERENCE DESIGNATION

## U.S. PATENT DOCUMENTS

EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUB- CLASS	FILING DATE IF APPROPRIATE
	AA						
	AB						
	AC						
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	AE						
	AF						
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							YES	NO
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	A M							
	AN							
	AO							
	AP							

## OTHER ART (Including Author, Title, Date, Pertinent Dates, Etc.)

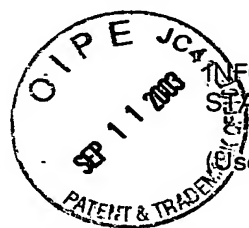
✓	AR	Ishibashi, M. et al., "Antiinflammatory and Antiarteriosclerotic Effects of Pioglitazone" Hypertension 40(5)(2002) 687-93 <u>Abstract</u>
✓	AS	Dandona, P. "Endothelium, inflammation, and diabetes" Curr Diab Rep 2(4) pp 311-5 (2002) <u>Abstract</u>
✓	AT	Breyer, Guan Y. "Peroxisome proliferator-activated receptors (PPARs): novel therapeutic targets in renal disease" Kidney Int. 60(1) (2001) pp 14-30 <u>Abstract</u>

EXAMINER

DATE CONSIDERED

EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

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							YES	NO
	AL							
	AM							
	AN							
	AO							
	AP							

## OTHER ART (Including Author, Title, Date, Pertinent Dates, Etc.)

✓	AP	Dubuquoy, L., et al. "Peroxisome proliferator-activated receptor (PPAR) gamma: a new target for the treatment of inflammatory bowel disease" Gastroenterol Clin Biol 24(8-9) (2000) pp 719-24 Abstract
✓	AS	Messier, Claude, et al. "Glucose regulation and cognitive functions: relation to Alzheimer's disease and diabetes" Behavioural Brain Research 75 (1996) pp 1-11
✓	AT	Hull, M., et al. "Pathways of inflammatory activation in Alzheimer's disease: potential targets for disease modifying drugs" Curr Med Chem 9(1) (2002) pp 83-8 Abstract

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## OTHER ART (Including Author, Title, Date, Pertinent Dates, Etc.)

✓	AR	Watson GS, et al. "The role of insulin resistance in the pathogenesis of Alzheimer's disease: implications for treatment" CNS Drugs 17(1) (2003) pp 27-45 <u>Abstract</u>
✓	AS	Kopelovich, L., et al. "Peroxisome proliferator-activated receptor modulators as potential chemopreventive agents" Mol Cancer Ther 1(5) (2002) pp 357-63 <u>Abstract</u>
✓	AT	Pershad Singh, H.A. "Pharmacological peroxisome proliferator-activated receptor ligands: emerging clinical indications beyond diabetes" Expert Opin. Invest. Drugs 8(11) (1999) pp 1859-1872 <u>Abstract</u>

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